UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WILLIAM S. M. WOLD, KAROLY TOTH, KONSTANTIN DORONIN and ANN E. TOLLEFSON

Appeal No. 2005-1444
Application No. 09/351,778

ON BRIEF

Before ADAMS, MILLS[1] and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

REQUEST FOR REHEARING

Appellants request reconsideration (rehearing) of the Board's Decision entered January 24, 2006, (Decision), wherein the examiner's rejections of the appealed claims under 35 U.S.C. § 112, first paragraph, § 102 and § 103 were affirmed.[2]

[1] The merits panel that issued the initial opinion in this case included Administrative Patent Judge Ellis, who retired from the U.S. Patent and Trademark Office before Appellants filed their Request for Rehearing. Administrative Patent Judge Mills has replaced Administrative Patent Judge Ellis on this merits panel. See In re Bose Corp., 772 F.2d 866, 227 USPQ 1 (Fed. Cir. 1985).

[2] Also before the panel for review was a rejection under 35 U.S.C. § 112, second paragraph, which rejection was affirmed. See Decision, pages 9-11. Appellants, however, do not request rehearing on that issue.

In their Request for Rehearing (Request), appellants make a series of assertions. We take each in turn.

I. The rejection of claims 32 and 104-106 under 35 U.S.C. § 112, first paragraph, should be reversed:

Appellants assert that the specification demonstrates the usefulness of cell lysis, virus release, and inhibition of cell spreading in assessing ADP overexpression. See Request, pages 15-16. As to cell lysis, appellants point to Example 2 of the specification as demonstrating the usefulness of cell lysis to assess ADP overexpression, and that in fact, "cell lysis assays were specifically used to confirm ADP overexpression in the claimed adenoviruses." Id. at 15 (emphasis in original). Appellants also point to page 25 of the specification as demonstrating that virus release assays were assessed as "'another means to measure cell lysis and to examine virus replication in cancer cells.'" Id. (emphasis in original). Finally, as to inhibition of cell spreading, appellants point to page 26 of the specification as demonstrating that virus release may be used to assess ADP overexpression. See id. at 16.

Upon reconsideration, we agree with appellants in this regard, and the rejection of claims 32 and 104-106 under 35 U.S.C. § 112, first paragraph, as containing new matter, is reversed.

II. The Board failed to establish a proper basis for its "Inherency" rejection:

Appellants argue that the only evidence relied upon by the Board, in affirming the rejections under § 102(b), "was the alleged similarity of methods by which the respective adenoviruses were made," but that the Board "apparently failed to

consider the evidence on the face of Henderson/Little . . . that demonstrated that their construct did not overexpress ADP." Request, page 4. According to appellants, ""inherency rejections are only proper where there is certainty with regard to the subject matter of the reference," and "comments such as 'absent evidence to the contrary' and 'would expect' evince a misapplication of the inherency doctrine, and an attempted shifting of burdens without a sufficient evidentiary basis." See id.

In the request, appellants reiterate their arguments made in the Appeal Brief that both Henderson and Little teach that CN751 expresses about the same amount of ADP as does wild-type adenovirus, and thus cannot be said to overexpress ADP. Therefore, as the claims require overexpression relative to *dl*309, and as *dl*309 according to appellants expresses "wild-type" levels of ADP, appellants submit that there is no reason, either explicit or inherent, to read Henderson or Little as providing ADP overexpression as required by the rejected claims. See id. at 5.

Appellants appear to have misapprehended the reasoning of the Board in affirming the § 102(e) rejections over Henderson and Little. As noted in the Decision at page 14, claim 13 recites that the "adenovirus vector . . . overexpresses an adenovirus death protein wherein in overexpression is defined as overexpression relative to *dl*309." The claim does not require a particular level of overexpression over that of *dl*309, thus all that is required by claim 13 is any measurable level of ADP expression over that of *dl*309. Thus, the panel read the claim as requiring overexpression of ADP, but construed the claim as requiring any level of overexpression, such as a 1% increase, over that of *dl*309.

As also set forth in the decision, there is enough evidence on the record demonstrating that such a level of overexpression would be inherent in the recombinant adenoviruses expressing ADP taught by Henderson and Little, thus the burden has been properly shifted to appellants to demonstrate that the adenoviruses of Little and Henderson do not meet that limitation. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (noting that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art products and claimed products are identical or substantially identical). Appellants prepare the adenoviruses required by the method of claim 13 by deleting the E3 region, and inserting the ADP gene from Ad5. See Specification, Example 1, page 20-21. Similarly, Henderson and Little also deleted the E3 region, and then inserted the ADP gene from Ad2. See Henderson, Col. 48, Example 6, lines 15-33; Little, Col. 38, Example 5, lines 20-25. As the adenoviruses taught by the Henderson and Little and those taught by the instant specification were constructed in an analogous manner, i.e., deletion of the E3 region followed by introduction of an ADP coding region, absent evidence to the contrary, one of ordinary skill in the art would expect the recombinant adenoviruses of Henderson and Little to express comparable amounts of ADP as the recombinant adenoviruses taught by the instant specification.

We note that in the Request, appellants have not addressed Best, nor the discussion of the evidence on the record that the adenoviruses taught by the Henderson and Little and those taught by the instant specification were constructed

in an analogous manner. See Decision, page 14. Appellants only response is that the only evidence relied upon by the Board is "the alleged similarity of methods by which the respective adenoviruses were made," but the record contains no evidence that contradicts the reasoning of the Board except appellants assertion that that both Henderson and Little teach that CN751 expresses about the same amount of ADP as does wild-type adenovirus, and thus cannot be said to overexpress ADP. But, as the comparison in Little and Henderson are to a wild type virus and not to *dl*309 as required by the instant claims;[3] as the adenoviruses taught by the Henderson and Little and those taught by the instant specification were constructed in an analogous manner; as the claims read on any level of overexpression as compared to *dl*309; and as the PTO does not have the resources to determine if the adenoviruses constructed by Henderson and Little meet the limitations of claim 13, the burden was properly shifted to appellants to demonstrate the adenoviruses as taught by Henderson and Little are different from the adenoviruses required by the method of claim 13.[4]

Accordingly, we are not persuaded by appellants' argument.

III. The Board failed to conduct a proper analysis to determine whether the patents cited as art under § 102(e) claim the same subject matter as the instant application:

Because we have reaffirmed our finding that the claims on appeal are anticipated § 102(e) by Henderson and Little, the issue becomes, as argued by

[3] We also point appellants' attention to the discussion on page 15 of the Decision that appellants' arguments in this regard are premised on the assumption that "cell killing is directly and always correlated to ADP overexpression," which discussion was not addressed by appellants in the Request.

appellants, that in order to demonstrate that the claims on appeal conflict with the Henderson/Little claims, a two-way analysis of patentable distinction must be performed, and that no such analysis was provided by the Board. See Request, pages 6-7. Appellants argue, at most, the Board has merely established one-way anticipation. Thus, appellants conclude, the Board erred in failing to consider the Rule 131 declarations submitted to remove Henderson and Little as prior art. See id. at 7.

> A 37 CFR § 1.131 affidavit is ineffective to overcome a United States patent or patent application publication, not only where there is a verbatim correspondence between claims of the application and of the patent, but also where there is no patentable distinction between the respective claims. In re Clark, 457 F.2d 1004, 173 USPQ 359 (CCPA 1972); In re Hidy, 303 F.2d 954, 133 USPQ 650 (CCPA 1962); In reTeague, 254 F.2d 145, 117 USPQ 284 (CCPA 1958); In re Ward, 236 F.2d 428,111 USPQ 101 (CCPA 1956); In re Wagenhorst, 62 F.2d 831, 16 USPQ 126(CCPA 1933).

MPEP § 715.05.

Thus, while a Rule 131 declaration may be used to antedate a reference that is prior art under 35 U.S.C. § 102(e), the panel notes, as explained above, that such a declaration is ineffective if there is no patentable distinction between the claims of the application and the claims of the patent being applied as prior art under 35 U.S.C. § 102(e), and in such a case, appellants only recourse is through interference proceedings. As provided in 37 CFR § 41.203(a), an interference exists if the subject matter of a claim of one party would, if prior art, have anticipated

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[4] We note that the first full paragraph of the Decision on page 13 refers to claims 11-12, 32-44, 101-106 and 108. The reference should have been to claims 11-13, 32-44, 101-106 and 108.

or rendered obvious the subject matter of a claim of the opposing party and vice versa. We agree with appellants that in order to determine if an interference exists, it must be determined if the instant claims anticipate or render obvious claims of the Henderson/Little patents, and if claims of the Henderson/Little patents anticipate or render obvious the claims on appeal.

As that analysis has not been made in the first instance, and as the board serves as a board of review, not a de novo examination tribunal, see 35 U.S.C. § 6(b) ("The [board] shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents."), we remand the case to the examiner to perform that analysis. In performing that analysis, the examiner may wish to consult with the interference specialist in the technical center. If the examiner determines that the two-way test has not been met, the examiner should state the reasons therefore on the record and return the case to the Board for consideration of the Rule 131 declarations.

FUTURE PROCEEDINGS

This remand to the examiner pursuant to 37 CFR § 41.50(a)(1) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)) is made for further consideration of a rejection. Accordingly, 37 CFR § 41.50(a)(2) applies if a supplemental examiner's answer is written in response to this remand by the Board.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (8th ed., rev. 3, August 2005). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REQUEST FOR REHEARING GRANTED-IN-PART; REMANDED

Donald E. Adams)
Administrative Patent Judge)
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Demetra J. Mills) APPEALS AND
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